

AUG 07 2002

1(021492

**TAB H**

**XIII. 510(k) Summary**

Pursuant to the Food and Drug and Cosmetic Act § 513(1)(B)(3)(A) as amended by the Safe Medical Device Act of 1990, this sponsor is providing a 510(k) Summary for the proposed device.

00-000068

## 510(k) SUMMARY

**Submitter** Personal Products Company Division of McNeil-PPC Inc.  
199 Grandview Road  
Skillman, New Jersey 08558-9418

**Contact Person** Marylou Panico  
Mgr. Regulatory Affairs  
(908) 904-3709 phone  
(908) 904-3748 fax

**Date Prepared** May 3, 2002

**Proprietary Name** K-Y® Brand  
WARMING LIQUID Personal Lubricant

**Common Name** Personal Lubricant

**Classification Name** Condom 21CFR § 884.5300 Product Code 85HIS

**Predicate Device** K-Y® Brand LIQUID Personal Lubricant

### **Description of Device**

K-Y® Brand WARMING LIQUID is a non-sterile clear non-staining, non-greasy, high viscosity liquid gel used as a personal lubricant. This product is highly lubricous and may be used with or without a latex condom during intimate sexual activity. K-Y® Brand WARMING LIQUID is not a contraceptive or spermicide. It is compatible with latex condoms as demonstrated in Condom Compatibility Testing conducted according the standards defined by ASTM D 3492.

### **Intended Use**

Patient lubricants are devices intended to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device. When used as an accessory to a medical device such as a condom, they are considered Class II Medical Devices.

K-Y® Brand WARMING LIQUID is principally intended as personal lubricant to supplement the body's own natural lubricating fluids, to moisturize, relieve friction and to enhance the ease and comfort of intimate sexual activity. This lubricant may be safely applied to vaginal, anal or penile tissue for purpose of lubrication, and moisturization. It is also compatible with latex condoms.

### **Technological Characteristics**

K-Y® Brand WARMING LIQUID formula is proprietary. The product is however has no exceptional technological characteristics consisting mainly of water soluble ingredients similar to other lubricants currently on the market.

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## **510(k) SUMMARY (continued)**

### **Substantial Equivalence**

This product has been shown in laboratory testing to be substantially equivalent to the currently marketed K-Y® Brand LIQUID Personal Lubricant. Both devices have the same intended use and similar formulas slightly varied ingredients. The unique feature of the K-Y® Brand WARMING LIQUID product is that this formula provides a warming sensation upon application. Comparable lubricity of the proposed K-Y® Brand WARMING LIQUID and the marketed K-Y® Liquid products was demonstrated in laboratory coefficient of friction testing.

### **Preclinical Testing of Formulation**

Preclinical biocompatibility studies on K-Y® Brand WARMING LIQUID was conducted by outside laboratories, in compliance with Good Laboratory Practices (GLPs) demonstrated:

- in a Dermal Sensitization Study that the product was considered not to be a contact sensitizing agent in albino guinea pigs.
- in a Rabbit Penile Irritation Study that the product did not cause any significant adverse effects when directly administered to the rabbit penis and based on macroscopic and microscopic findings did not produce any significant irritation.
- in a 10-Day Rabbit Vaginal Irritation Study, that the product did not cause any pharmacotoxic effects when administered vaginally to rabbits for 10 consecutive days. K-Y® Brand WARMING LIQUID was minimally irritating to the rabbit vaginal epithelium but considered acceptable for use in humans.
- in a Mouse Systemic Injection Study that a 25% w/v the product did not cause mortality and was not associated with systemic toxicity when administered at 50mg/kg using the i.p. route of administration.

### **Clinical Testing**

In a Human 21-Day Cumulative Irritation Assay, this product under occluded conditions was considered to be only mildly irritating and elicited no evidence of sensitization on the skin of healthy humans.

In a Human Repeat Insult Patch Test (Modified Draize Procedure), this product was compared to the currently marketed K-Y® Liquid for its potential for contact sensitization. This study concluded that K-Y® Brand WARMING LIQUID was considered essentially non-irritating and did not elicit evidence of sensitization on healthy human skin.

A Two-Phase Consumer Use Study provided data on consumer (Males and Females) perception of warmth with a single application of the K-Y® Brand WARMING LIQUID product at the test facility, as well as actual use at home during sexual activity. Female subjects received gynecological examinations at baseline and following the last intercourse episode. The study was conducted in compliance with 21CFR 812 for Investigational Device Exemption. This study concluded that, greater than 85% of the participants perceived a warming sensation while using the product. Additionally, after one week of home use, (with a minimal of two sexual intercourse encounters) there was no observed irritation upon gynecological examination.

Preclinical and Clinical testing conducted on this formulation has demonstrated scientific evidence that this product is safe for its intended use.

00-000070



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Marylou Panico  
Manager, Regulatory Affairs  
Personal Products Company  
Division of McNeil-PPC, Inc.  
199 Grandview Road  
SKILLMAN NJ 08558

Re: K021492  
Trade/Device Name: K-Y °Brand WARMING LIQUID™  
Personal Lubricant  
Regulation Number: 21 CFR 880.6375  
Regulation Name: Patient lubricant  
Regulation Number: 21 CFR 884.5300  
Regulation Name: Condom  
Regulatory Class: II  
Product Code: 85 MMS and HIS  
Dated: May 8, 2002  
Received: May 9, 2002

Dear Ms. Panico:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

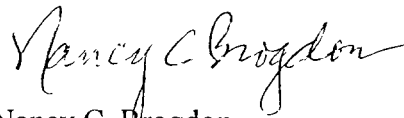
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**510(k) INDICATIONS FOR USE FORM**  
**(Replica of FDA Form)**

510(k) Number (if known): K021492

Device Name: K-Y® Brand  
WARMING LIQUID™ Personal Lubricant

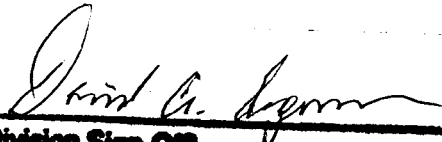
Indications For Use:  
Personal Lubricant (compatible with latex condoms)

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_ OR Over-the-Counter-Use ✓  
(per 21 CFR 801.109)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K021492